



# Frequently Asked Questions about the COVID-19 Vaccines

## **Q** What is Emergency Use Authorization and how is that different from FDA approval?

**A** An Emergency Use Authorization (EUA) is a process by which the US Food and Drug Administration (FDA) can authorize a preventive, diagnostic, or therapeutic agent or device by an expedited process during a declared Public Health Emergency, such as the current COVID-19 pandemic. There must be good evidence that the benefits outweigh any risks. For a vaccine to obtain an EUA, there still must be the normal three-phase testing process to determine safety and effectiveness. Most safety concerns with vaccines will show up in the first 6 weeks after they are administered. The FDA has required that all vaccines must have at least 2 months of safety data after the full vaccine course is administered in Phase three clinical trial to apply for an EUA. More information is available on the [FDA's website](#).

## **Q** What are the planned phases of COVID-19 vaccine distribution?

**A** Currently, there is not enough approved vaccine available for everyone in the country. Vaccine distribution has been prioritized according to those who are at high risk. Each local authority (usually at the state, Tribal, or local level) can prioritize distribution based on local situations, but in general, this is the priority guidance for the country:

Phase one includes about 15% of the US population, and is further subdivided:

Phase 1a – Healthcare workers, first responders, and long-term care facility staff and residents

Phase 1b – Adults who have multiple health problems that put them at high risk

Phase two will include about 30 to 35% of the population and will include the vulnerable workforce, everyone 65 and older, and people who have health problems that put them at moderate risk.

Phase three will include about 40 to 45% of the population and will cover most of the rest of the country, including people in less vulnerable jobs (those not having much public contact).

Phase four will include about 10 to 15% of the population and will include those at the lowest risk.

More information is available on the [CDC's website](#).

## **Q** Are there different vaccines for COVID-19?

**A** There are currently two vaccines that have received Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA), one made by Pfizer/BioNTech and the other made by Moderna. Both are mRNA vaccines, and both require two doses spaced 3 to 4 weeks apart to be fully effective. Although the vaccines are similar, they are not interchangeable; in other words, people will need to get the same vaccine for both doses. In the coming year, it is anticipated that several more vaccines will obtain a EUA from the FDA.

## **Q** Why are there different COVID-19 vaccines?

**A** There are approximately 330 million people in the US and almost eight billion people in the world. With current technology, no single vaccine can be made fast enough to cover eight billion people in a timely fashion. To end the pandemic, most of the world's population will need to be vaccinated. That is why we need multiple vaccines. Also, until they are fully tested in a Phase 3 trial, it is not known how effective and safe a vaccine will be. That is another reason that multiple vaccines are being developed.

## **Q** Are the COVID-19 vaccines approved for use in children?

**A** The Pfizer/BioNTech vaccine is approved for people aged 16 and over. The Moderna vaccine is approved for people 18 and over. Both vaccines are conducting trials in adolescents 12 and over, but it will be weeks or months before the safety and effectiveness data is available for these ages. If the vaccines prove to be safe and effective for 12 and over, they will then be tested on younger children, but we are months away from having an approved vaccine for younger children.



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**Q** What are some of the logistics of the COVID-19 vaccine distribution and administration?

**A** The mRNA vaccines are very fragile and are not stable for long at room temperature. The Pfizer/BioNTech vaccine requires ultra-cold storage that is not achievable with regular freezers (-70 degrees C, or 94 below 0 F). The Moderna vaccine must also be kept frozen, but not quite as cold (-20 degrees C, or -4 F). This presents challenges in shipping and storing. Both vaccines come in preservative-free, multi-dose vials (five dose vials for the Pfizer/BioNTech vaccine, and 10 dose vials for the Moderna vaccine). Once the vaccine is thawed, it must be used quickly (within 6 hours once the vial is pierced), so the administration must be carefully planned to avoid wasting any vaccine.

**Q** How is the Indian Health Service distributing vaccines?

**A** The Indian Health Service (IHS) receives an allocation of vaccine from the federal government allocation system, then distributes that allocation based on population. For USET Tribal Nations, 4,275 doses of vaccine (975 doses of the Pfizer/BioNTech, and 3,300 doses of the Moderna) are anticipated to be received in the first shipment, enough to cover healthcare workers and nursing home residents or who the Tribal Nation considers a high priority. Additional shipments of the vaccine will follow in the coming weeks. Tribal Nations also have the option of procuring vaccine through their state, and some have opted to do this.

**Q** Do the COVID-19 vaccines prevent transmission of the virus by asymptomatic carriers?

**A** For the vaccines currently available (Pfizer/BioNTech and Moderna) this is unknown. The Phase 3 trials of these vaccines were designed to see how effective the vaccine was at keeping people from getting sick from the virus. The trials did not specifically test to see if they prevented transmission of the virus from asymptomatic individuals to other people. Until more is known about this, we must assume that they do not protect against the asymptomatic spread of the virus. For this reason, mask-wearing and social distancing will still be critically important for vaccinated persons as well as unvaccinated.

**Q** Once COVID-19 vaccinations start, can things go back to normal (life pre-pandemic)?

**A** Unfortunately, it will be a long time before things get back to normal. In order for the pandemic to end, there will have to be enough people with good immunity to the virus to stop it from spreading. Vaccination is our best hope for achieving this. But it will take a long time to vaccinate the vast majority of the nearly eight billion human inhabitants of the planet. Even when the pandemic eventually ends, there will probably still be sporadic outbreaks of COVID-19. This will require a strong public health infrastructure to effectively deal with.

**Q** Why do we need to obtain a critical mass target reach community immunity?

**A** Community immunity, also called herd immunity, for COVID-19 can only happen when a certain percentage of people become immune or vaccinated. Right now, we don't know the exact percentage of the population that needs to be vaccinated to stop transmission of COVID-19. However, science from past vaccines and the data available on COVID-19, such as its ability to spread and cause infections in people, shows that between 70 to 90% of the population would need to be vaccinated to reach community immunity and end the pandemic. Until this percentage is reached—whatever it turns out to be—it is recommended to continue to follow social distancing guidelines and wear a mask when you are outside of your house.